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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,547	08/27/2003	Carsten-Peter Carstens	25436/1243	5516
27495	7590	08/24/2005	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS / STR 111 HUNTINGTON AVENUE BOSTON, MA 02199			MCGILLEM, LAURA L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,547	CARSTENS, CARSTEN-PETER	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 8/27/2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 11 is/are allowed.
- 6) Claim(s) 1-10 and 12-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/12/2004, 8/12/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

It is noted that this application is a divisional application of Application No. 09/793,372 filed 02/26/2001, now U.S. Patent No. 6,696,278. Claims 1-19 are pending.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The zip code of the post office address for Inventor Carstens has been changed, but the change has not been initialed by the inventor.

Drawings

Figure 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 33, the specification refers to SEQ ID NO:1 on Figure 6. However, there are only five figures in the disclosure. Appropriate correction is required.

The use of the trademark STRATAPREP has been noted in this application on page 32. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The claimed subject matter of claims 4, 12, 13 and 19 which states "wherein in one or both of said first and second vectors there is no second site specific recombinase recognition site between said double-stranded origin of replication and said site-specific recombinase recognition site" is not disclosed in the remainder of the specification. In addition, in Claim 10 the strA gene is listed as a selectable marker but it is not disclosed in the remainder of the specification. The claims as filed in the original application are part of the disclosure and therefore, the applicant may amend

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the specification to include the claimed subject matter. *In re Benno*, 768 F2d 1340,226 USPQ 683 (Fed Cir 1985).

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 recites the phrase "initiate replication "as" said double stranded" wherein the word "as" appears to be a typo, and it appears that the word "at" is meant. Appropriate correction is required.

Claim 14 is objected to because of the following informalities: Claim 14 has a double period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 9, 12-13 and 19 are vague and indefinite because it is not clear in what way the second vector comprises a negative selectable marker. It would be remedial to amend the claim to recite " a gene encoding a negative selectable marker."

Claim 6 is vague and indefinite because it recites a limitation of claim 4 "wherein said site-specific recombinase recognition site is selected from the group consisting of"

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and there are multiple site-specific recombination sites listed in claim 4. It is not clear whether each of the site-specific recombinase recognition sites in the first and second vectors of claim 4 must have the same recognition sites or whether they may have site-specific recombinase recognition sites that are different from each other.

Claim 7 is vague and indefinite because it recites a limitation of claim 4 identifying the double stranded origin of replication as being from the filamentous bacteriophage f1. Since the first and second vector each have a double-stranded origin of replication, it is not clear whether each of the double-stranded origin of replications in the first and second vectors of claim 4 must both be from the filamentous bacteriophage f1 or whether one may be from a different source.

Claim 8 is vague and indefinite because it recites a limitation of claim 4 identifying the double stranded origin of replication as being from plasmid pKym. Since the first and second vector each have a double-stranded origin of replication, it is not clear whether each of the double-stranded origin of replications in the first and second vectors of claim 4 must both be from the plasmid pKym or whether one may be from a different source.

Claim 1 is vague and indefinite because the metes and bounds of the limitation "interposed between" are not clear in the phrase "gene of interest interposed between said double-stranded origin of replication of said second vector and said site-specific recombination recognition site, said single-stranded origin of replication of said second vector, and said gene encoding said second selectable marker." The definition of an "interposed" gene of interest is disclosed in the specification (pages 7-8) as: "a nucleic

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acid molecule which has, immediately adjacent to its 5' most end, either a double-stranded origin of replication of a rolling circle replicon or a site-specific recombination recognition site, and has immediately adjacent to its 3' most end whichever of the double-stranded origin of replication of a rolling circle replicon or site-specific recombination recognition site that is not immediately adjacent to the 5' most end." It is clear from this definition that the gene of interest is interposed between two elements immediately adjacent on either side. As claim 1 is written, it is apparent that the gene of interest is adjacent on one side to the double-stranded origin of replication of said second vector; however, it is not clear which of the next three listed elements (i.e. the site-specific recombination recognition site, the single-stranded origin of replication of said second vector, and the gene encoding said second) are on the other side of the gene of interest so that the gene of interest would be "interposed between" the elements.

Claim 1 is vague and indefinite because it does not establish a functional link between the introduction of a rep protein which initiates replication and formation of the product vector. It is not clear from the claim language how introduction of a rep protein and the initiation of replication produce a product vector.

Conclusion

Claim 11 is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
8/19/2005


DAVID GUZO
PRIMARY EXAMINER